IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

VIVIAN and ROBERT ZALE,
individually and as husband and wife,

Plaintiffs,

v.

MERCK & CO., INC.,
A New Jersey Corporation,

Defendant.

JURY TRIAL DEMANDED

Civil Action No.:

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**COMPLAINT**

Plaintiffs, Vivian Zale and Robert Zale, individually and as husband and wife, by and through the undersigned attorneys, hereby file this Complaint against Defendant, MERCK & CO., INC., (hereinafter referred to as "Defendant'"), and allege as follows:

**PARTIES**

1. Plaintiff, Vivian Zale, was born on August 27, 1940, and is a resident of the city of Englewood, Sarasota County, State of Florida. Plaintiff used FOSAMAX from August 1997 through and including the latter part of 1998.

2. Plaintiff, Vivian Zale, was married to Robert Zale at all times material to this action. Plaintiff, Robert Zale, is a resident of the city of Englewood, Sarasota County, State of Florida.

3. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey.

4. Defendant was at all relevant times authorized to conduct business in the State of Florida.

5. Defendant has regularly transacted business in the State of Florida and continues to do so.

6. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

7. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of Florida.

8. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Florida.

9. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of Florida.

## JURISDICTION AND VENUE

10. The amount in controversy in this matter exceeds $75,000.00, exclusive of interest and costs.

11. This Court has jurisdiction under 28 U.S.C. §1332 because the parties are of diverse citizenship and the amount in controversy meets or exceeds the statutory minimum.

12. Venue is proper under 28 U.S.C. §1391(a) because a significant portion of the material events giving rise to this action occurred in Sarasota County, Florida.

## FACTUAL BACKGROUND

13. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

14. In September 1995, the United States Food and Drug Administration ("FDA") approved Defendant's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant as FOSAMAX.

15. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.

16. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for FOSAMAX confirms that the molecule contains a nitrogen atom.

17. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Defendant knew or should have know that FOSAMAX, as a nitrogenous bisphosphonate,

shared a similar adverse event profiles to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

18. Defendant knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Defendant knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

19. Defendant also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

20. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

21. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

22. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

23. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

24. Since FOSAMAX was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX.

25. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

26. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

27. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw.

28. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw on patients using FOSAMAX, Defendant continues to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

29. FOSAMAX is one of Defendant's top selling drugs, averaging more than $3 billion a year in sales.

30. Consumers, including Plaintiff, Vivian Zale, who have used FOSAMAX for treatment of osteoporosis, had several alternative safer products available to treat the conditions.

31. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff, Vivian Zale, or the medical community, of such risks.

32. As a direct result, Plaintiff, Vivian Zale, was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff, Vivian Zale, required and will in the future require ongoing medical care and treatment.

33. Plaintiff, Vivian Zale, has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

34. Plaintiff, Vivian Zale, was prescribed and began taking FOSAMAX in August 1998 and continued to take FOSAMAX throughout the latter part of 1998.

35. Plaintiff, Vivian Zale, used FOSAMAX as prescribed and in a foreseeable manner.

36. As a direct and proximate result of using FOSAMAX, Plaintiff, Vivian Zale, suffered severe osteonecrosis of the jaw.

37. Plaintiff, Vivian Zale, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

38. Plaintiff, Vivian Zale, used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

39. Plaintiff, Vivian Zale, would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff, Vivian Zale, would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

40. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff, Vivian Zale, and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

41. As a result of Defendant's actions, Plaintiff, Vivian Zale, and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff, Vivian Zale, had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

## COUNT I

## STRICT LIABILITY

42. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

43. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff, Vivian Zale.

44. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, Vivian Zale, without substantial change in the condition in which it was manufactured and sold by Defendant.

45. Plaintiff, Vivian Zale, used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

46. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, Vivian Zale, including when it was used as intended and in a reasonably foreseeable manner.

47. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

48. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

49. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, Vivian Zale, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

50. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

51. Plaintiff, Vivian Zale, could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

52. As a direct and proximate consequence of Defendant's conduct, Plaintiff, Vivian Zale, sustained osteonecrosis of the jaw. In addition, Plaintiff, Vivian Zale, required and will continue to require healthcare. Plaintiff, Vivian Zale, has incurred and will continue to incur medical and related expenses. Plaintiff, Vivian Zale, also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff, Vivian Zale, has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

53. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, Vivian Zale, thereby entitling Plaintiff, Vivian Zale, to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs request judgment against Defendant for damages in excess of $75,000, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

## COUNT II

## NEGLIGENCE

54. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

55. Defendant owed Plaintiff, Vivian Zale, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

56. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a) failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b) failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c) failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d) designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, Vivian Zale, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e) failing to exercise due care when advertising and promoting FOSAMAX; and

f) negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

57. As a direct and proximate consequence of Defendant's conduct, Plaintiff, Vivian Zale, sustained osteonecrosis of the jaw. In addition, Plaintiff, Vivian Zale, required and will continue to require healthcare. Plaintiff, Vivian Zale, has incurred and will continue to incur medical and related expenses. Plaintiff, Vivian Zale, also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff, Vivian Zale, has

incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

58. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, Vivian Zale, thereby entitling Plaintiff, Vivian Zale, to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs request judgment against Defendant for damages in excess of $75,000, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

## COUNT III

## NEGLIGENT MISPREPRESENTATION

59. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

60. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a) Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b) Defendant represented that FOSAMAX was safer than other alternative medications.

61. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the

safety and risk of FOSAMAX to consumers, including Plaintiff, Vivian Zale, and the medical community.

62. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, Vivian Zale, rely upon them.

63. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

64. Plaintiff, Vivian Zale's doctors, and others relied upon the representations.

65. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff, Vivian Zale.

66. As a direct and proximate consequence of Defendant's conduct, Plaintiff, Vivian Zale, sustained osteonecrosis of the jaw. In addition, Plaintiff, Vivian Zale, required and will continue to require healthcare. Plaintiff, Vivian Zale, has incurred and will continue to incur medical and related expenses. Plaintiff, Vivian Zale, also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff, Vivian Zale, has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

67. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, Vivian Zale, thereby entitling Plaintiff, Vivian

Zale, to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs request judgment against Defendant for damages in excess of $75,000, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

## COUNT IV

## FRAUDULENT CONCEALMENT

68. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

69. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a) Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b) Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

70. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

71. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

72. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, Vivian Zale, rely upon them.

73. Plaintiff, Vivian Zale's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from said doctors and Plaintiff, Vivian Zale.

74. As a direct and proximate consequence of Defendant's conduct, Plaintiff, Vivian Zale, sustained osteonecrosis of the jaw. In addition, Plaintiff, Vivian Zale, required and will continue to require healthcare. Plaintiff, Vivian Zale, has incurred and will continue to incur medical and related expenses. Plaintiff, Vivian Zale, also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff, Vivian Zale, has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

75. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, Vivian Zale, thereby entitling Plaintiff, Vivian Zale, to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs request judgment against Defendant for damages in excess of $75,000, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

## COUNT V

## BREACH OF IMPLIED WARRANTY

76. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

77. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

78. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

79. Defendant was aware that consumers, including Plaintiff, Vivian Zale, would use FOSAMAX for treatment of osteoporosis and for other purposes.

80. Plaintiff, Vivian Zale, and the medical community reasonably relied upon the judgment and sensibility of Defendant to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

81. Defendant breached its implied warranty to consumers, including Plaintiff, Vivian Zale, FOSAMAX was not of merchantable quality or safe and fit for its intended use.

82. Consumers, including Plaintiff, Vivian Zale, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

83. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

84. As a direct and proximate consequence of Defendant's conduct, Plaintiff, Vivian Zale, sustained osteonecrosis of the jaw. In addition, Plaintiff, Vivian Zale, required and will continue to require healthcare. Plaintiff, Vivian Zale, has incurred and will continue to incur medical and related expenses. Plaintiff, Vivian Zale, also has suffered and will

continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff, Vivian Zale, has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

85. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, Vivian Zale, thereby entitling Plaintiff, Vivian Zale, to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs request judgment against Defendant for damages in excess of $75,000, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

## COUNT VI

## BREACH OF EXPRESS WARRANTY

86. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

87. Defendant expressly represented to Plaintiff, Vivian Zale and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

88. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

89. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

90. Plaintiff, Vivian Zale, other consumers, and the medical community relied upon Defendant's express warranties.

91. As a direct and proximate consequence of Defendant's conduct, Plaintiff, Vivian Zale, sustained osteonecrosis of the jaw. In addition, Plaintiff, Vivian Zale, required and will continue to require healthcare. Plaintiff, Vivian Zale, has incurred and will continue to incur medical and related expenses. Plaintiff, Vivian Zale, also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff, Vivian Zale, has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

92. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, Vivian Zale, thereby entitling Plaintiff, Vivian Zale, to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs request judgment against Defendant for damages in excess of $75,000, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

## COUNT VII

## LOSS OF CONSORTIUM

93. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

94. Plaintiff, Robert Zale, was at all relevant times the lawful husband of Vivian Zale.

95. As a result of the injuries suffered by Vivian Zale, Robert Zale lost the care, comfort, society, attention, companionship, and consortium of Vivian Zale.

WHEREFORE, Plaintiffs request judgment against Defendants for damages in excess of $75,000, together with costs, interest, punitive damages, and any further legal or equitable relief this Court deems appropriate.

## COUNT VIII

## INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

96. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

97. Defendant placed FOSAMAX into the stream of commerce and/or kept FOSAMAX in the stream knowing that FOSAMAX was not safe for its intended purposes and knowing that FOSAMAX had caused and/or could cause attendant medical problems described herein.

98. The acts, omissions, and representations of Defendant regarding the manufacturing, distribution, and marketing of FOSAMAX as described in the foregoing paragraphs were intentional, reckless, extreme and outrageous. Defendant intentionally engaged in extreme and outrageous conduct when it intentionally and/or recklessly marketed FOSAMAX, and then intentionally and/or recklessly concealed information

from Plaintiff, Vivian Zale, and her treating physicians about causing severe and permanent injuries.

99. As a direct and proximate consequence of Defendant's conduct, Plaintiff, Vivian Zale, sustained osteonecrosis of the jaw. In addition, Plaintiff, Vivian Zale, required and will continue to require healthcare. Plaintiff, Vivian Zale, has incurred and will continue to incur medical and related expenses. Plaintiff, Vivian Zale, also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff, Vivian Zale, has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

100. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, Vivian Zale, thereby entitling Plaintiff, Vivian Zale, to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs request judgment against Defendant for damages in excess of $75,000, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

## COUNT IV

## NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

101. Plaintiffs restate and reallege the allegations contained in Paragraphs 1 through 41 above as if fully set forth herein.

102. Defendant negligently and carelessly:

a) manufactured, distributed, advertised, promoted, and sold FOSAMAX

b) manufactured, tested, sold and/or distributed, advertised and/or promoted FOSAMAX to Plaintiff, Vivian Zale, and her physicians;

c) concealed the danger of FOSAMAX from Plaintiff, Vivian Zale, and her physicians; and

d) misrepresented the quality, safety, and usefulness of FOSAMAX.

103. Defendant's negligence and carelessness directly impacted and directly involved Plaintiff, Vivian Zale, in that she ingested FOSAMAX, a defective and dangerous medication manufactured, sold, distributed, and promoted by Defendant causing Plaintiff, Vivian Zale, to suffer emotional distress.

104. As a direct and proximate consequence of Defendant's conduct, Plaintiff, Vivian Zale, sustained osteonecrosis of the jaw. In addition, Plaintiff, Vivian Zale, required and will continue to require healthcare. Plaintiff, Vivian Zale, has incurred and will continue to incur medical and related expenses. Plaintiff, Vivian Zale, also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff, Vivian Zale, has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

105. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, Vivian Zale, thereby entitling Plaintiff, Vivian

Zale, to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs request judgment against Defendant for damages in excess of $75,000, together with costs, punitive damages, interest, and any further legal or equitable relief this Court deems appropriate.

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand a jury trial as to all claims triable in this action.

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Trial Counsel for Plaintiffs

**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**Tampa Division**

Case Number: 8:08-CV- 879-T-27MAP

VIVAN ZALE, et al.

v.

MERCK & CO., INC.
_____/

**NOTICE OF DESIGNATION UNDER LOCAL RULE 3.05**
**AND CASE MANAGEMENT NOTICE**

Please take notice that, in accordance with Local Rule 3.05, this action is designated as a Track **TWO** Case. Plaintiff is responsible for serving a copy of this notice and any attachment to this notice upon all other parties. All parties must meet any requirements established in Local Rule 3.05 for cases designated on this track and utilize the attached Case Management Report form.

The Court advises the parties of the following:

1. Most Track TWO cases will be tried within twelve (12) to eighteen (18) months of the filing date.
2. Pre-trial conference will be conducted approximately thirty (30) days prior to trial.
3. Dispositive motion deadline will be scheduled ninety (90) days prior to pre-trial conference.
4. Discovery cut-off and expert witness disclosure deadlines will be as agreed to in the case management report unless specifically excepted in the Case Management and Scheduling Order.

On Monday, July 12, 2004, the United States District Court for the Middle District of Florida converted to a mandatory paperless electronic filing system: CM/ECF. The Court requires parties to utilize the Court's CM/ECF system in all actions pending before this Court, no later than 15 days after appearing in an action.

JAMES D. WHITTEMORE
United States District Judge

By: Anne H. Ohle, Deputy Clerk

Distribution:
-Copies to plaintiff(s) (including bankruptcy appellant(s), and removing defendant(s))
-Case Management Report form attached

**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**Tampa Division**

Case Number: 8:08-CV- 879-T-27MAP

VIVAN ZALE, et al.

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MERCK & CO., INC.
_____/

AMENDED
**NOTICE OF DESIGNATION UNDER LOCAL RULE 3.05**
**AND CASE MANAGEMENT NOTICE**

Please take notice that, in accordance with Local Rule 3.05, this action is designated as a Track **TWO** Case. Plaintiff is responsible for serving a copy of this notice and any attachment to this notice upon all other parties. All parties must meet any requirements established in Local Rule 3.05 for cases designated on this track and utilize the attached Case Management Report form.

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JAMES D. WHITTEMORE
United States District Judge

By: Anne H. Ohle, Deputy Clerk

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

v. Case Number:

_____/

**CASE MANAGEMENT REPORT**

1. Meeting of Parties: Pursuant to Local Rule 3.05(c)(2)(B) or (c)(3)(A), a meeting was held on _____ (date) at _____ (time) (check one) (__) by telephone (or) (__) at _____ (place) and was attended by:

_____ Name _____ Counsel for (if applicable

2. Initial Disclosures:

a. Fed. R. Civ. P. 26(a)(1) as amended December 1, 2000 provides that "[e]xcept in categories of proceedings specified in Rule 26(a)(1)(E), or to the extent otherwise stipulated or directed by order, a party must, without awaiting a discovery request, provide to other parties: (A) the name and, if known, the address and telephone number of each individual likely to have discoverable information that the disclosing party may use to support its claims or defenses, unless solely for impeachment, identifying the subjects of the information; (B) a copy of, or a description by category and location of, all documents, data compilations, and tangible things that are in the possession, custody, or control of the party and that the disclosing party may use to support its claims or defenses, unless solely for impeachment; (C) a computation of any category of damages claimed by the disclosing party, making available for inspection and

copying as under Rule 34 the documents or other evidentiary material, not privileged or protected from disclosure, on which such computation is based, including materials bearing on the nature and extent of injuries suffered; and (D) for inspection and copying as under Rule 34 any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in the action or to indemnify or reimburse for payments made to satisfy the judgment." Fed. R. Civ. P.26(a)(1).[1]

The parties (check one)

_____ have exchanged information referenced by Fed. R. Civ. P. 26(a)(1)(A)-(D) or agree to exchange such information on or before _____ (date).[2]

_____ stipulate to not disclose information referenced by Fed. R. Civ. P. 26(a)(1)(A)-(D) for the specific reason(s) that:

_____
_____
_____

_____ have been unable to reach agreement on whether to disclose information referenced by Fed. R. Civ. P. 26(a)(1)(A)-(D). (Identify party or parties) _____ objects to disclosure of such information for the specific reason(s) that:

_____
_____
_____

A party must make its initial disclosures based on the information then reasonably available to it and is not excused from making its disclosures because it has not fully completed its investigation of the case or because it challenges the sufficiency of another party's disclosures or because another party has not made its disclosures. See Fed. R. Civ. P. 26(a)(1).

Information referenced by Fed. R. Civ. P. 26(a)(1)(A)-(D) must be made "at or within 14 days of the Rule 26(f) conference unless a different time is set by stipulation or court order, or unless a party objects during the conference that initial disclosures are not appropriate in the circumstances of the action and states the objection in the Rule 26(f) discovery plan." Fed. R. Civ. P. 26(a)(1). Any party first served or otherwise joined after the Rule 26(f) conference must make these disclosures within 30 days after being served or joined unless a different time is set by stipulation or court order. See Fed. R. Civ. P. 26(a)(1).

3. Discovery Plan - Plaintiff: The parties jointly propose the following Plaintiff's discovery plan:

a. Plaintiff's Planned Discovery: A description of every discovery effort Plaintiff plans to pursue is described below. The description of each discovery effort will be listed under the appropriate heading below and will include the subject matter of the discovery and the time during which the discovery will be pursued:

(1) Requests for Admission:

Number of Requests for Admission: Parties may seek to limit the number of Plaintiff's requests for admission in accordance with Fed. R. Civ. P. 26(b)(2). Any such request must be made in paragraph 6 below and approved by the court.

(2) Written Interrogatories:

Number of Interrogatories: Local Rule 3.03(a) provides "[u]nless otherwise permitted by the Court for cause shown, no party shall serve upon any other party, at one time or cumulatively, more than twenty-five (25) written interrogatories pursuant to Rule 33, Fed.R.Civ.P., including all parts and subparts." Any request by Plaintiff to exceed this limit must be made in paragraph 6 below and approved by the court.

(3) Requests for Production or Inspection:

(4) Oral Depositions:

Number of Depositions: Local Rule 3.02(b) provides, "[i]n accordance with Fed. R. Civ. P. 30(a)(2)(A) and 31(a)(2)(A), no more than ten depositions per side may be taken in any case unless otherwise ordered by the Court." Any request by Plaintiff to exceed this limit must be made in paragraph 6 below and approved by the court.

Time Permitted for Each Deposition: Each deposition is limited to one day of seven hours in accordance with Fed. R. Civ. P. 30(d)(2) unless extended by agreement of the parties or order of Court.

The parties stipulate/request a court order to extend the time to take the deposition of the following individuals:

| Name | Proposed length of Deposition | Grounds |
|---|---|---|

b. Disclosure of Non-Expert Testimony: Parties stipulate that they will disclose all non-expert witnesses by the date listed below (no later than sixty (60) days prior to pre-trial conference):

c. Disclosure of Expert Testimony: Parties stipulate, in accordance with Fed. R. Civ. P. 26(a)(2)(C), that Plaintiff's Fed. R. Civ. P. 26(a)(2) disclosure will be due as noted here:

d. Supplementation of Disclosures and Responses: Parties agree that Plaintiff's supplementation under Fed. R. Civ. P. 26(e) will be provided at the following times:

e. Completion of Discovery: Plaintiff will commence all discovery in time for it to be completed on or before _____ (date).

4. Discovery Plan - Defendant: The parties jointly propose the following Defendant's discovery plan:

a. Defendant's Planned Discovery: A description of every discovery effort Defendant plans to pursue is described below. The description of each discovery effort will be listed under the appropriate heading below and will include the subject matter of the discovery and the time during which the discovery will be pursued:

(1) Requests for Admission:

Number of Requests for Admission: Parties may seek to limit the number of Defendant's requests for admission in accordance with Fed. R. Civ. P. 26(b)(2). Any such request must be made in paragraph 6 below and approved by the court.

(2) Written Interrogatories:

Number of Interrogatories: Local Rule 3.03(a) provides "[u]nless otherwise permitted by the Court for cause shown, no party shall serve upon any other party, at one time or cumulatively, more than twenty-five (25) written interrogatories pursuant to Rule 33, Fed.R.Civ.P., including all parts and subparts." Any request by Defendant to exceed this limit must be made in paragraph 6 below and approved by the court.

(3) Requests for Production or Inspection:

(4) Oral Depositions:

Number of Depositions: Local Rule 3.02(b) provides, "[i]n accordance with Fed. R. Civ. P. 30(a)(2)(A) and 31(a)(2)(A), no more than ten depositions per side may be taken in any case unless otherwise ordered by the Court." Any request by Defendant to exceed this limit must be made in paragraph 6 below and approved by the court.

Time Permitted for Each Deposition: Each deposition is limited to one day of seven hours in accordance with Fed. R. Civ. P. 30(d)(2) unless extended by agreement of the parties or order of Court.

The parties stipulate/request a court order to extend the time to take the deposition of the following individuals:

| Name | Proposed length of Deposition | Grounds |
|---|---|---|

b. Disclosure of Non-Expert Testimony: Parties stipulate that they will disclose all non-expert witnesses by the date listed below (no later than sixty (60) days prior to pre-trial conference):

c. Disclosure of Expert Testimony: Parties stipulate, in accordance with Fed. R. Civ. P. 26(a)(2)(C), that Defendant's Fed. R. Civ. P. 26(a)(2) disclosure will be due as noted here:

d. Supplementation of Disclosures and Responses: Parties agree that Defendant's supplementation under Fed. R. Civ. P. 26(e) will be provided at the following times:

e. Completion of Discovery: Defendant will commence all discovery in time for it to be completed on or before _____ (date).

5. Joint Discovery Plan - Other Matters: Parties agree on the following other matters relating to discovery (*e.g.*, handling of confidential information, assertion of privileges, whether discovery should be conducted in phases or be limited to or focused upon particular issues):

6. Disagreement or Unresolved Issues Concerning Discovery Matters: Any disagreement or unresolved issue will not excuse the establishment of discovery completion dates. The parties are unable to agree as to the following issues concerning discovery:

7. Third Party Claims, Joinder of Parties, Potentially Dispositive Motions: Parties agree that the final date for filing motions for leave to file third party claims, motions to join parties, motions for summary judgment, and all other potentially dispositive motions should be _____. (Note time limit in Local Rule 4.03.)

8. Settlement and Alternative Dispute Resolution: Pursuant to Local Rule 3.05(c)(2)(C)(v), the parties submit the following statement concerning their intent regarding Alternative Dispute Resolution:

Parties agree that settlement is
___ likely (check one)
___ unlikely.

Parties agree to consent to binding arbitration pursuant to Local Rules 8.02(a)(3) and 8.05(b). _____yes _____no _____likely to agree in future

If binding arbitration is not agreed to, the court may order nonbinding arbitration pursuant to Chapter Eight of the Local Rules of the Middle District of Florida, mediation pursuant to Chapter Nine of the Local Rules of the Middle District of Florida, or both.

9. Consent to Magistrate Judge Jurisdiction: The parties agree to consent to the jurisdiction of the United States Magistrate Judge for final disposition, including trial. See 28 U.S.C. § 636.
_____yes _____no _____likely to agree in future

10. Preliminary Pretrial Conference:
Track Three Cases: Local Rule 3.05(c)(3)(B) provides that preliminary pretrial conferences are mandatory in Track Three Cases.

Track Two Cases: Parties
____request (check one)
____do not request

a preliminary pretrial conference before entry of a Case Management and Scheduling Order in this Track Two case. Unresolved issues to be addressed at such a conference include:

11. Final Pretrial Conference and Trial: Parties agree that they will be ready for a final pretrial conference on or after _____(date) and for trial on or after _____(date). This **Jury** ____ **Non-Jury** _____ trial is expected to take approximately _____ hours.

12. Pretrial Disclosures and Final Pretrial Procedures: Parties acknowledge that they are aware of and will comply with pretrial disclosures requirements in Fed. R. Civ. P. 26(a)(3) and final pretrial procedures requirements in Local Rule 3.06.

13. Other Matters:

Date: _____

Signature of Counsel (with information required by Local Rule 1.05(d)) and Signature of Unrepresented Parties

_____

_____

_____

_____

_____

_____

_____

# UNITED STATES DISTRICT COURT

_____ District of _____

Plaintiff
V.

Defendant

NOTICE, CONSENT, AND ORDER OF REFERENCE — EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE

Case Number:

## NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE TO EXERCISE JURISDICTION

In accordance with the provisions of 28 U.S.C. §636(c), and Fed.R.Civ.P. 73, you are notified that a United States magistrate judge of this district court is available to conduct any or all proceedings in this case including a jury or nonjury trial, and to order the entry of a final judgment. Exercise of this jurisdiction by a magistrate judge is, however, permitted only if all parties voluntarily consent.

You may, without adverse substantive consequences, withhold your consent, but this will prevent the court's jurisdiction from being exercised by a magistrate judge. If any party withholds consent, the identity of the parties consenting or withholding consent will not be communicated to any magistrate judge or to the district judge to whom the case has been assigned.

An appeal from a judgment entered by a magistrate judge shall be taken directly to the United States court of appeals for this judicial circuit in the same manner as an appeal from any other judgment of this district court.

## CONSENT TO THE EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE

In accordance with provisions of 28 U.S.C. §636(c) and Fed.R.Civ.P. 73, the parties in this case consent to have a United States magistrate judge conduct any and all proceedings in this case, including the trial, order the entry of a final judgment, and conduct all post-judgment proceedings.

| Party Represented | Signatures | Date |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

## ORDER OF REFERENCE

IT IS ORDERED that this case be referred to _____ United States Magistrate Judge, to conduct all proceedings and order the entry of judgment in accordance with 28 U.S.C. §636(c) and Fed.R.Civ.P. 73.

_____ Date

_____ United States District Judge

NOTE: RETURN THIS FORM TO THE CLERK OF THE COURT ONLY IF ALL PARTIES HAVE CONSENTED ON THIS FORM TO THE EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE.

Inasmuch as no objection is pending at this time, the stay is lifted.

JUN 10 2008

CLERK'S OFFICE
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

JUDGE KEENAN

JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

MAY 23 2008

FILED
CLERK'S OFFICE

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

08 CV 5377

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SDNY
6/17/08

**IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION**

Vivian Zale, et al. v. Merck & Co., Inc., )
M.D. Florida, C.A. No. 8:08-879 ) MDL No. 1789

## CONDITIONAL TRANSFER ORDER (CTO-57)

On August 16, 2006, the Panel transferred four civil actions to the United States District Court for the Southern District of New York for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 444 F.Supp.2d 1347 (J.P.M.L. 2006). Since that time, 128 additional actions have been transferred to the Southern District of New York. With the consent of that court, all such actions have been assigned to the Honorable John F. Keenan.

It appears that the action on this conditional transfer order involves questions of fact that are common to the actions previously transferred to the Southern District of New York and assigned to Judge Keenan.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), this action is transferred under 28 U.S.C. § 1407 to the Southern District of New York for the reasons stated in the order of August 16, 2006, and, with the consent of that court, assigned to the Honorable John F. Keenan.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Southern District of New York. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:

Jeffery N. Lüthi
Clerk of the Panel

A CERTIFIED TRUE COPY

JUN 10 2008

ATTEST
FOR THE JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

A CERTIFIED COPY
J. MICHAEL McMAHON, CLERK

BY
DEPUTY CLERK